Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SERGAZY M. ADEKENOV, and KANAT A. AITUGANOV

Appeal No. 2002-0518 Application No. 08/934,471

ON BRIEF

Before WINTERS, ADAMS, and GRIMES, <u>Administrative Patent Judges</u>.

ADAMS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, and 5-8 which are all the claims pending in the application.

Claims 1 and 8 are illustrative of the subject matter on appeal and are reproduced below:

- A pharmaceutical composition in unit dosage form suitable for the treatment of a human cancer, consisting essentially of about 40 mg to about 480 mg of dimethylaminoarglabin or a pharmaceutically acceptable salt thereof.
- 8. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is therapeutically effective for suppressing tumor growth in a human, and wherein said packaging material comprises a label that indicates that said pharmaceutical agent can be used for suppressing tumor growth in a human, and

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wherein said pharmaceutical agent comprises dimethylaminoarglabin or a pharmaceutically acceptable salt thereof.

The reference relied upon by the examiner is:

USSR State Registry of Inventions Certificate:

Adekenov et al. (Adekenov)

1746674

Mar. 8, 1992

GROUND OF REJECTION

Claims 1 and 5-8 stand rejected under 35 U.S.C. § 103 as being unpatentable over Adekenov.

We reverse.

DISCUSSION

According to the examiner (Answer, page 3), Adekenov "teaches applicant's compound, dimethyl amino arglabin [sic], for treating tumors and a pharmaceutical composition containing said compound." We agree that Adekenov teaches the compound, dimethylaminoarglabin, set forth in appellants' claimed invention. Appellants' claims 1 and 5-7, however, require that the claimed pharmaceutical composition consist essentially of a specific amount (dose) of dimethylaminoarglabin. To reach this dosage limitation, the examiner finds (Answer, page 4), "[t]he amounts employed in ... [Adekenov] are higher than those being employed by [a]ppelants (note the 30-50 mg/kg is the max tolerable dose in the certificate)." The examiner, however, makes no attempt to explain how this 30-50 mg/kg amount correlates to the amounts set forth in claims 1 and 5-7. See e.g., claim 1, which requires 40 mg to about 480 mg of dimethylaminoarglabin. Accordingly, it is our opinion that the examiner failed to

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meet his burden of providing the evidence necessary to establish a <u>prima facie</u> case of obviousness.

Similarly, with regard to the article of manufacture set forth in appellants' claim 8, the examiner simply concludes (Answer, page 4), "[t]he article of manufacture, claim 8, is nothing more than a pharmaceutical composition with packaging materials." While this is may be true, the examiner's burden of providing an evidentiary basis for his rejection is not relieved. On this record, the examiner makes no attempt to provide the evidence necessary to establish a prima facie case of obviousness.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a <u>prima facie</u> case of obviousness. <u>In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "A <u>prima facie</u> case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." <u>In re Bell</u>, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (<u>quoting In re Rinehart</u>, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). If the examiner fails to establish a <u>prima facie</u> case, the rejection is improper and will be overturned. <u>In re Fine</u>, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

The examiner's unsupported assertion is not sufficient to support a <u>prima</u> facie case of obviousness. See In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). See also W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1552, 220 USPQ 303, 312-313 (Fed. Cir.

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1983): "To imbue one of ordinary skill in the art with knowledge of the invention..., when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."

Since the examiner failed to provide the requisite evidentiary basis to support his rejection we are constrained to reverse the rejection of claims 1 and 5-8 under 35 U.S.C. § 103 as being unpatentable over Adekenov.

REVERSED

Sherman D. Winters Administrative Patent Judge)))
Donald E. Adams Administrative Patent Judge)) BOARD OF PATENT
)) APPEALS AND
) INTERFERENCES
Lora M. Green Administrative Patent Judge)))

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